

# PRIA Renegotiation Form

Decision	Registration Number	Petition
579048	93182-5	

Chemical Name	GHARDA PERMETHRIN TECHNICAL
Company Name	GHARDA CHEMICALS INTERNATIONAL INC.
Fee Category	R352
PRIA Decision Time Frame	8M
Original PRIA Due Date	2022-07-11
Proposed New PRIA Due Date	2022-11-14
Current and Previous Negotiated Dates	2022-10-11

## Negotiated Due Date Reason

<b>Additional Data Required:</b>	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other	
<b>Comments:</b>	

<b>Data Deficiencies:</b>	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
<b>Comments:</b>	

<b>Late Risk Assessment:</b>	
<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	

<b>Interim Considerations:</b>	
<input checked="" type="checkbox"/> Agency Initiated <input checked="" type="checkbox"/> Registrant Initiated	

☐ 11-3 Deficiencies need to be addressed
 ☐ Endangered Species Concerns
 ☐ Data Not Submitted
 ☐ Failure to Respond to Deficiencies
 ☒ Other - Comment Field
 ☐ Risk Issues Environmental
 ☐ Risk Issues Human Health
 ☐ CSF
 ☐ Label
 ☐ Public Process
 ☐ Impurities Review
 ☐ Administrative-FR Notice
 ☐ Other - No Reason Selected in Webform

### Summary of Deficiency Type(s)

☒ Agency Initiated
 ☒ Registrant Initiated

Is "Fix" in-house? Yes

### Describe Interactions with Company(Describe when Contacted and Company's Response including response to Previous Negotiated Due Dates: )

The company was contacted on September 26, 2022 to ask about the status of their submission of a revised data matrix. The registrant responded on September 27, 2022 that he is having difficulties with ensuring he can submit correct information and asked for some help. The registrant agreed to a new PRIA date of November 14, 2022 on September 28, 2022.

"75 Date" Letter Sent?	No
Reason for None	No deficiencies identified that would need a 75-day letter.
Registrant Notified that this is the Last Negotiation?	NA

**Rationale for Proposed Due Date:** The company agreed to an additional 30 days because of extenuating circumstances happening which held up the company's resubmission - (Health/Hurricane Ian)

**Issue(s) Describe in Detail:** This was previously renegotiated from 7/11/2022 to 10/11/2022 to allow time for company to address deficiencies with the data matrix/selective citation of data to support me-too new uses being added to the label. The company needs more time to fix the data matrix and update the label. The company is adding a variety of label language that is present on another product's label, and the proposed data matrix was missing the required studies. The registrant contact also became sick with Covid and then Hurricane Ian hit which resulted in the registrant evacuating as well as loss of power. The additional 30 days should allow time to review a revised data matrix and make any needed corrections.

**Comment(s):**

<b>Approved /Disapproved:</b>	Approved
<b>Date of Final Decision</b>	Sat Oct 08 07:52:55 EDT 2022 Michael Goodis (MGOODIS) from IO (Host IP Address: 161.80.29.84)

<b>e-Signature:</b> Michael Goodis (MGOODIS) from IO (Host IP Address: 161.80.29.84)
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